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09/674,824	11/06/2000	Horst Loerz	514413-3848	5275
20999	7590	06/19/2003	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151				CHEN, SHIN LIN
ART UNIT		PAPER NUMBER		
1632				DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/674,824

Applicant(s)

Loerz et al.

Examiner
Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 6, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above, claim(s) 7, 13, and 17-26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6, 8-12, 14-16, and 27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Applicants' amendment filed 5-6-03 has been entered. Claims 1-6, 9-12 and 14-16 have been amended. Claim 27 has been added. Claims 1-27 are pending and claims 1-6, 8-12, 14-16 and 27 are under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 8-12, 14-16 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 5-6-03 necessitates this new ground of rejection.

The phrase "under stringent conditions" in claims 1, 6 and 27 is vague and renders the claims indefinite. It is unclear as to the metes and bounds of what would be considered "under stringent conditions". The specification only provide example of stringent conditions (see page a, line 23) but fails to specifically define "stringent conditions". The specific stringent condition has to be defined in the specification or in the claims. Claims 2-5, 8-12 and 14-16 depend on claim 1 but fail to clarify the indefiniteness.

The phrase "wherein a **cosuppression** effect is achieved" in claim 10 lines 2-3 is vague and renders the claim indefinite. The term "cosuppression" indicates there are more than one

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suppression effect. It is not clear whether the “cosuppression effects” is obtained from two different regulatory elements or from regulatory elements and other source. If a suppression effect comes from other source, it is unclear what this “other source” is.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 8-12 and 14-16 remain rejected and claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). Applicant's arguments filed 5-6-03 have been fully considered but they are not persuasive.

Applicants amended claims to recite “under the stringent conditions”. The newly added claim 27 reads on an isolated nucleic acid molecule comprising nucleotides 9-570 of SEQ ID No. 1 or a ribonucleotide sequence corresponding therewith, a nucleic acid molecule which hybridizes under stringent conditions with said isolated nucleic acid molecule or nucleotide sequence encoding SEQ ID No. 2, and a nucleic acid molecule whose nucleotide sequence

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deviates from the nucleic acid molecules set forth above owing to the degeneracy of the genetic code.

Applicants argue that the claims have been amended to recite "under stringent conditions" and US Patent Nos. 6,548,065, 6,403,373 and 6,159,731 all have same kind of hybridization languages in the issued claims (amendment, p. 6). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). As discussed above, the phrase "under stringent conditions" is vague and indefinite. It is unclear as to the metes and bounds of what would be considered "under stringent conditions". The claims still read on adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 1, or deleting or substituting the nucleotide sequence of SEQ ID No. 1. A nucleic acid molecule comprising nucleotides 9-570 of SEQ ID No. 1, which is a part of SEQ ID No. 1, can be any gene, either known or unknown and unidentified gene. The scope of the claims include various known, and unknown and unidentified genes that either encodes or not encodes a polypeptide. The structures of the those various genes have not been disclosed and there is no known or disclosed correlation between function and structure of the non-described regulatory elements and untranslated regions of the gene. Furthermore, there is no additional disclosure of physical and/or chemical properties. The specification also fails to provide the structural features of the nucleic acid molecule encoding a protein having a wheat starch synthase activity. Thus, one skilled in the art at the time of the invention would not be able to envision all the nucleic acid molecules encompassed in the claims. In addition, each

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patent application is considered individually because different patent applications have different subject matters, different states of the prior art, nature of the inventions, and disclosure in the specifications. Therefore, the claim languages of different patent applications or issued patents can not be extrapolated to the present invention.

5. Claims 1-6, 8-12 and 14-16 remain rejected and claim 27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising the sequence of SEQ ID No. 1, does not reasonably provide enablement for any nucleic acid molecule comprising part of nucleotide sequence of SEQ ID No. 1, any nucleic acid molecule which hybridizes under stringent conditions with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1, wherein said nucleic acid molecule encodes a protein having the function of a wheat starch synthase, a vector comprising said nucleic acid molecule, a host cell transformed with said nucleic acid molecule or said vector, and a process of using said nucleic acid molecule, vector, and host cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). Applicant's arguments filed 5-6-03 have been fully considered but they are not persuasive.

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Applicants amended claims to recite "under the stringent conditions". The newly added claim 27 reads on an isolated nucleic acid molecule comprising nucleotides 9-570 of SEQ ID No. 1 or a ribonucleotide sequence corresponding therewith, a nucleic acid molecule which hybridizes under stringent conditions with said isolated nucleic acid molecule or nucleotide sequence encoding SEQ ID No. 2, and a nucleic acid molecule whose nucleotide sequence deviates from the nucleic acid molecules set forth above owing to the degeneracy of the genetic code.

Applicants argue that the specification teaches how to isolate a nucleic acid that hybridizes under stringent conditions to SEQ ID No. 1 or nucleotide sequence encoding SEQ ID No. 2 and claim 1 recites the structure of the claimed nucleic acid molecules. Applicants further argue that the functional limitation of the nucleic acid molecule is the function of wheat starch synthase and the specification teaches how to identify said starch synthase (amendment, p. 6-7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). The claims read on adding unknown nucleotide sequence at 5', 3' ends and/or within the nucleotide sequence of SEQ ID No. 1, or deleting or substituting the nucleotide sequence of SEQ ID No. 1. The scope of the claims include various known, and unknown and unidentified genes that either encodes or not encodes a polypeptide. The claims also encompass various nucleic acid molecules encoding a genus of numerous structural variants of the amino acid sequence of SEQ ID No. 2 having a starch synthase activity. The specification fails to provide adequate guidance and evidence whether the claimed nucleic acid molecules

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would encode proteins having the function of a wheat starch synthase. The specification also fails to provide adequate guidance and evidence that a nucleic acid molecule hybridizing "under stringent conditions" with nucleic acid encoding the amino acid sequence of SEQ ID No. 2 or nucleic acid comprising the nucleotide sequence of SEQ ID No. 1 or a part of SEQ ID No. 1 would have the function of a wheat starch synthase. There is no evidence of record regarding the structural and functional requirements of the polypeptide of SEQ ID No. 2 and its variants, and protein function is unpredictable from mere amino acid sequence. It would be unpredictable whether the polypeptides encoded by the claimed nucleic acid molecules would have the function of a wheat starch synthase. Therefore, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5 and 6 remain rejected and claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Block et al., 1996, GenEmbl Accession No. U48227 (computer printout, page 11, 12) and is repeated for the reasons set forth in the preceding Official action mailed 11-1-

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02 (Paper No. 12). Applicant's arguments filed 5-6-03 have been fully considered but they are not persuasive.

Applicants amended claims to recite "under the stringent conditions". The newly added claim 27 reads on an isolated nucleic acid molecule comprising nucleotides 9-570 of SEQ ID No. 1 or a ribonucleotide sequence corresponding therewith, a nucleic acid molecule which hybridizes under stringent conditions with said isolated nucleic acid molecule or nucleotide sequence encoding SEQ ID No. 2, and a nucleic acid molecule whose nucleotide sequence deviates from the nucleic acid molecules set forth above owing to the degeneracy of the genetic code.

Applicants argue that Block only discloses a fragment of the claimed molecule and there is not evidence that the nucleotide sequence taught by Block encodes a protein with wheat starch synthase activity (amendment, p. 7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). Block teaches a **wheat Triticum aestivum soluble starch synthase** mRNA sequence, GenEmbl Accession No. U48227, which is 100% identical to base 718-2771 of SEQ ID No. 1. Since it is a **wheat soluble starch synthase** mRNA sequence, the protein encoded by said sequence would have wheat starch synthase activity. Further, since GenEmbl Accession No. U48227 is 100% identical to base **718-2771** of SEQ ID No. 1, i.e. more than 2000 bases identical to SEQ ID No. 1, the sequence of GenEmbl Accession No. U48227 will hybridize to nucleotide sequence of SEQ ID

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No. 1 under stringent condition. Thus, claims 1-3, 5 and 6 remain anticipated and claim 27 is anticipated by Block.

8. Claims 1-6, 8, 9, 12 and 14-16 remain rejected and claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Block, 1997 (WO 97/45545, IDS-AF, and computer printout, page 5, 6) and is repeated for the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). Applicant's arguments filed 5-6-03 have been fully considered but they are not persuasive.

Applicants argue that Block teaches soluble starch synthase II (SSII), which is different from SSI and the nucleotide sequence taught by Block will not hybridize under stringent conditions to the nucleic acid molecules claimed in parts (a) or (b) of claim 1 (amendment, p. 7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-1-02 (Paper No. 12). Block teaches a **wheat soluble starch synthase** cDNA sequence (SEQ ID No. 1 of WO 97/45545), Geneseq Accession No. AAV01527, which is 100% identical to base **533-2771** of SEQ ID No. 1. Since it is a **wheat soluble starch synthase** cDNA sequence, the protein encoded by said sequence would have wheat starch synthase activity. The claims do not specify the encoded protein must have SSI activity. SSI and SSII are both starch synthases. Further, since Geneseq Accession No. AAV01527 is 100% identical to base **533-2771** of SEQ ID No. 1, i.e. more than 2000 bases identical to SEQ ID No. 1, the sequence of Geneseq Accession No. AAV01527 will hybridize to nucleotide sequence of SEQ ID No. 1

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under stringent condition. Thus, claims 1-6, 8, 9, 12 and 14-16 remain anticipated and claim 27 is anticipated by Block.

Conclusion

No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

S. Chen